EXHIBIT F

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

ALIGN TECHNOLOGY, INC., Plaintiff, v. CLEARCORRECT OPERATING, LLC, CLEARCORRECT HOLDINGS, INC., & INSTITUT STRAUMANN AG, Defendants.	Civil Action No. 6:24-cv-187-ADA-DTG
CLEARCORRECT OPERATING, LLC, CLEARCORRECT HOLDINGS, INC., & STRAUMANN USA, LLC, Counterclaim-Plaintiffs, v. ALIGN TECHNOLOGY, INC., Counterclaim-Defendant.	

EXPERT DECLARATION OF DR. WILLIAM HARRELL, JR. DMD IN SUPPORT OF CLEARCORRECT'S OPENING CLAIM CONSTRUCTION BRIEF

I. Introduction

1. My name is Dr. William Harrell, Jr. I have been retained by ClearCorrect Operating LLC, ClearCorrect Holdings, Inc., and Institut Straumann AG (collectively, "ClearCorrect") to serve as an expert in this case.

2. I understand that Align Technology, Inc. ("Align") has accused ClearCorrect of infringing certain claims in U.S. Patent Nos. 10,973,613 (the "'613 patent"), 11,154,384 (the "'384 patent"), 11,648,090 (the "'090 patent"), 11,648,091 (the "'091 patent,"), 8,038,444 (the "'444 patent"), 10,456,217 (the "'217 patent"), 10,524,879 (the "'879 patent"), 11,369,456 (the "'456 patent" and with the '444, '217, and '879 patents, collectively the "Treatment Planning Patents").

3. I have been asked for my conclusions concerning certain disputed claim terms in the Treatment Planning Patents. I have reviewed those patents and their prosecution histories.

4. I am being compensated for my time at my standard consulting rate of $900 an hour. My compensation is not dependent on the conclusions expressed in this Declaration or the outcome of this matter.

5. In the last four years, I have not testified as an expert at trial or by deposition in any case.

6. If requested, I expect to testify regarding the conclusions set forth in this Declaration.

II. Background and Qualifications

7. My qualifications, including a list of publications authored in the previous 10 years, are listed in my CV which is attached as Exhibit A.

8. My education and professional background is in orthodontics, dentistry, temporomandibular joint (TMJ) therapy, and sleep medicine.

9. I am currently a practicing orthodontist at Harrell Orthodontics, a company that I started in 1977. In my nearly fifty years of practicing, I have seen more than 10,000 patients and have used aligner-related technology to treat more than 500 patients.

10. In addition to being a practicing orthodontist, I teach at the University of Alabama School of Dentistry in Birmingham, Alabama in the Department of Orthodontics. I have taught since 2018 and teach classes relating to Orthodontics, Airway, Sleep Disorders Breathing, TMJ Disorders, 3D Imaging including CBCT, 3D face scanning, Intraoral Scanning, various treatment techniques including early treatment, conventional orthodontic therapy, invisible aligner therapy, braces, etc. More information about my teaching experience is detailed in my CV, including other universities, societies, and associations I have taught and/or lectured at.

11. I receive my B.S. in Chemistry & Math with a minor in Biology in 1971 from the University of Alabama in Tuscaloosa, Alabama. I received my DMD from the University of Alabama School of Dentistry, Birmingham, Alabama in 1975, and received my Certificate in Orthodontics from the University of Pennsylvania, School of Dental Medicine in 1977.

12. I am Board Certified by the American Board of Orthodontics (ABO) since 1989. I am also member of the American Dental Association (ADA), American Association of Orthodontists (AAO), American Academy of Dental Sleep Medicine (AADSM), and many other professional associations.

13. As my CV shows, I am also a member of numerous other professional organizations including The Southeastern Dental Practice Research Network (DPBRN), The Royal Society of Medicine – Great Britain, The Foundation for Orthodontic Research (FOR), and The Orthodontic Education and Research Foundation (OERF).

14. I have also published various articles and textbook chapters related to 3D imaging, ConeBeam CT (CBCT), TMJ diagnosis and therapy using splints, braces, and invisible aligners, and other areas in dentistry and/or orthodontics. Also, I am the main Editor of a textbook to be published in 2025 by Springer Publishing, "Pediatric and Adult Breathing Disorders of Sleep: interdisciplinary diagnosis, management and prevention." These are listed on my CV.

15. In my practice, I have used clear aligners for at least 20+ years. I was the first to use Invisalign in Alabama in and around 1996-97, when it first came out. These clear aligners have included aligners from Align (e.g., Invisalign), ClearCorrect, Orthosnap, and AOA Labs (the Red, the White & Blue system). I currently use uLab and Dandy clear aligners in my practice.

III. Legal Principles

16. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my conclusions expressed herein. My understanding of the law is as follows.

A. Claim Construction

17. I understand that patent claim terms are generally given their ordinary and customary meaning. That is the meaning the term would have for a person of ordinary skill in the art at the time of the claimed invention—i.e., when the application for the patent was filed.

18. I understand that claim terms should be understood in the context of the claim as a whole. I further understand that the patent's specification is relevant to the meaning of a claim term. I understand that the claims must be read in light of the specification. I also understand that the file history may be considered when interpreting the meaning of a patent's claims.

19. I understand that the claim language, specification, and file history are called "intrinsic evidence," and are the most important tools for determining the meaning of a claim term. I also understand that other evidence, such as testimony from the inventors named on the

patent at issue, dictionaries, treaties, and other evidence of the understanding of persons of ordinary skill in the art can be relevant in determining how a person of ordinary skill in the art would understand the claims. I understand that this evidence, which is called "extrinsic evidence," should be considered in the context of the intrinsic evidence and cannot be used to change the meaning of a claim term to be inconsistent with the intrinsic evidence. Evidence and opinions from an expert in the field regarding a claim term's meaning are another type of extrinsic evidence.

B. Indefiniteness

20. I have been informed and understand the Patent Act (35 U.S.C. § 112 ¶ 2) requires a patent specification to conclude with claims "particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." I understand that a patent claim that does not meet this standard is invalid as indefinite. I understand that a claim is indefinite if, when read in light of the patent specification and prosecution history, the claim fails to inform a person of ordinary skill in the art, with reasonable certainty, about the scope of the claimed invention. I understand that absolute or mathematical precision is not required in a claim, but a claim must, when read in light of the specification and the prosecution history, provide objective boundaries for those of skill in the art.

IV. Overview of the Treatment Planning Patents

21. Each of the Treatment Planning Patents is titled "Automated Treatments Staging for Teeth," lists Ian Kitching, Alexander Dmitriev, and Alexey Vishnevskiy as the named inventors, and identifies Align Technology, Inc. as the assignee.

22. I understand that the Treatment Planning Patents claim priority to two provisional applications (U.S. Provisional Application Nos. 60/824,022 and 60/824,024), which were both filed on August 30, 2006.

23. The Abstract of '444 patent states:

> Apparatus, system, and methods for utilizing one or more computing devices to stage the movement of teeth during an alignment treatment are disclosed. The computing device receives an electronic representation of the patient's teeth in their initial position and an electronic representation of the teeth a final position for each tooth. A route each tooth will travel to reach its final position is determined, and the teeth are scheduled to move according to a movement pattern. Moreover, the schedule of movement takes into account a maximum rate of tooth movement for each tooth, the path of movement for each tooth, the distance each tooth needs to move, any needed tooth staggering, any needed round-tripping or tooth movement slowing. The invention also includes techniques for determining an optimum number of stages for the treatment based on the schedule of movement.

24. As the "Detailed Description of the Invention" states, prior applications and patents "describe techniques for generating 3-dimensional digital data sets containing models of individual components of a patient's dentition," that these "data sets include digital models of individual teeth and the gingival tissue surrounding the teeth," and that "these applications also describe computer-implemented techniques for using the digital models in designing and simulating an orthodontic treatment plan for the patient."[1]

25. The '444 patent also describes "a plurality of patterns and options available to a system user and a computing device for optimizing the movement of a patient's teeth during treatment."[2]

A. The Pattern Terms

26. The '444 patent identifies five specific pattern terms: All-equal, A-shaped, V-shaped, mid-line shift, and M-shaped pattern (the "Pattern Terms").

27. I understand that the parties have agreed to the construction of an All-equal pattern, which closely tracks the definition of an all-equal pattern provided in the '444 patent at column

[1] '444 patent, 3:10-19.
[2] '444 patent, 5:29-32.

6:51-56: "A pattern where all of a patient's teeth move in parallel with one another (i.e., all of the patient's teeth that need to move begin moving at the same stage, and finish moving at the same stage)."

1. "V-Shaped" Pattern

28. The '444 patent states that:

> For a set of teeth lacking space in between at least two teeth (i.e., over-crowding), the program is configured to utilize a "V-shaped" pattern in staging a set of aligners to correct the teeth. In accordance with one exemplary embodiment of the invention, the 'V-shaped' pattern provides that teeth having the same and/or similar positions on the arch will be moved beginning at the same stage, and will move continuously until they reach their final position. Moreover, the 'V-shaped' pattern begins by moving the most posterior-positioned teeth (e.g., the molars, or teeth in position 7 and/or 8) then sequentially moving the next anterior-positioned teeth until all of the teeth reach their final position. The next anterior-positioned teeth are not scheduled to begin moving until at least approximately the half-way stage of its respective posterior-positioned tooth.[3]

29. The '444 patent states that "FIG 5 is a diagram of an exemplary embodiment of a 'V-shaped' pattern for moving the crowded teeth of a patient during an orthodontic treatment."[4] Figure 5 is reproduced below.

[3] '444 patent, 9:12-26.

[4] '444 patent, 2:44-46; *see also* '444 patent, 9:42-51 ("FIG. 5 is a diagram illustrating an example of a "V-shaped pattern 500 in accordance with one exemplary embodiment of the invention. Similar to above, column 510 illustrates the number of stages needed to correct the patient's teeth. In this example, the patient requires 20 stages of treatment before the patient's teeth reach their final position in stage 21. Moreover, similar to FIGS. 3 and 4, FIG. 5 uses the standard teeth numbering system 520 to identify each of the teeth and a position 530 to illustrate the respective positioning of the teeth on the patient's arch.").

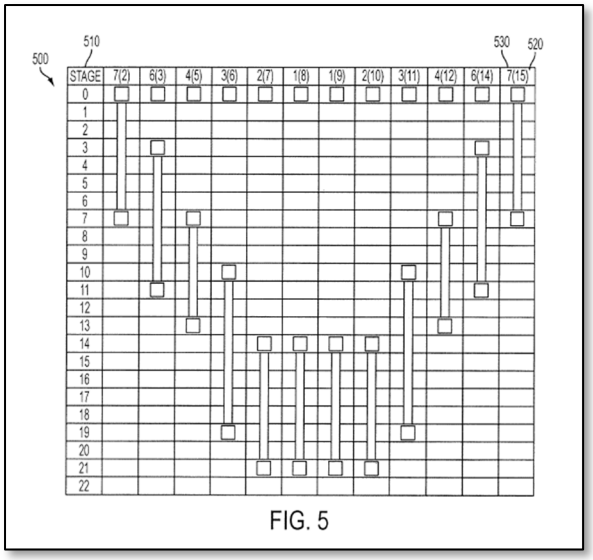


FIG. 5

2. "A-Shaped" Pattern

30. The '444 patent states that:

> For a set of teeth having gaps between at least two posterior teeth, the program is configured to utilize an "A-shaped" pattern in staging a set of aligners to correct the teeth. In accordance with one exemplary embodiment of the invention, the "A-shaped" pattern provides that teeth having the same and/or similar positions on the arch will be moved beginning at the same stage, and will move continuously until they reach their final position. Moreover, the "A-shaped pattern" begins by moving the most anterior-positioned teeth (e.g., the incisors, or teeth in positions 1 and/or 2) then sequentially moving the next posterior-positioned teeth until all of the teeth reach their final position.[5]

31. The '444 patent states that "FIG 4 is a diagram of one exemplary embodiment of an 'A-shaped' pattern for moving the gapped teeth of a patient during an orthodontic treatment."[6]

Figure 4 is reproduced below.

[5] '444 patent, 7:47-58.

[6] '444 patent, 2:40-43; '444 patent, 8:26-35 (providing additional description of Figure 4);'444 patent, 13:37-46 ("Recall in FIG. 4, tooth 7 is scheduled to move 8 stages. In this example, tooth 7 is moved out of the way of tooth 8 for 3 stages (i.e., stages 1 through 3), tooth 8 takes 4 stages to pass through tooth 7's previous position (i.e., stages 4 through 7), tooth 7 is moved back 3 stages to return to its previous position (i.e., stages 8 through 10), and then tooth 7 is moved its originally scheduled 8 stages (i.e., stages 11 through 18) to reach its final position in stage 19. Similarly, recall in FIG. 4 that tooth 9 is also scheduled to move 8 stages.").

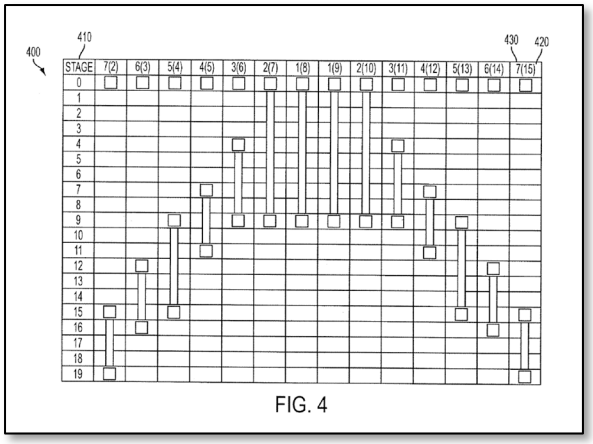


FIG. 4

3. "M-Shaped" Pattern

32. The '444 patent states that:

> For a set of teeth having gaps between posterior teeth and anterior teeth, the program is configured to utilize an "M-shaped" pattern in creating a set of aligners to correct the teeth. In accordance with one exemplary embodiment of the invention, the "M-shaped" pattern provides that teeth having the same and/or similar positions on the arch will be moved beginning at the same stage, and will move continuously until they reach their final position. Moreover, the "M-shaped" pattern begins by moving teeth between the anterior teeth and the posterior teeth (e.g., the bicuspids, or teeth in positions 4 and/or 5) then sequentially moving both the adjacent anterior and/or adjacent posterior teeth until all of the teeth reach their final position. Furthermore, the teeth, e.g., incisors, move simultaneously unless they will collide with or obstruct one another, wherein the incisors may be 'staggered', 'round tripped', and/or slowed (discussed below) to prevent them from colliding with one another. In addition, similar to embodiments discussed above, subsequently scheduled teeth are not scheduled to begin moving until at least approximately the half-way stage of its respective precedent tooth. Moreover, the corresponding positions on each side of the patient's arch move during the same stage. In accordance with an aspect of one exemplary embodiment, no more than two posterior teeth on one side of the arch may move simultaneously.[7]

[7] '444 patent, 11:41-65.

33. The ’444 patent states that “FIG 7 is a diagram of one exemplary embodiment of an ‘M-shaped’ pattern for moving the gapped teeth of a patient during an orthodontic treatment.”[8] Figure 7 is reproduced below.

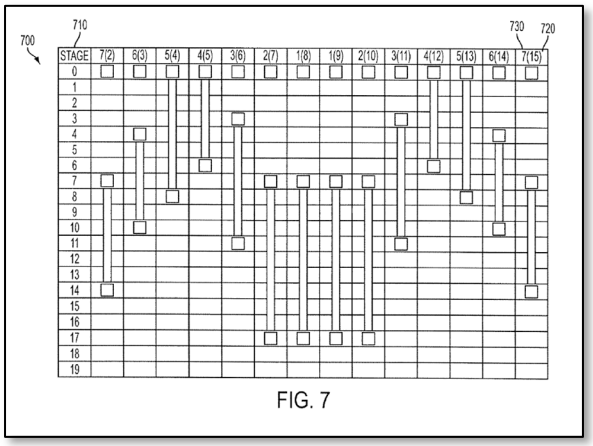


FIG. 7

4. “Mid-Line Shift” Pattern

34. The ’444 patent states that:

> For a set of teeth that is off-centered (i.e., skewed to one side), the program is configured to utilize a “mid-line shift” pattern in staging a set of aligners to correct the teeth. In accordance with one exemplary embodiment of the invention, the mid-line shift pattern provides that tooth movement begins on one side of the patient’s arch to center the teeth with respective to the mid-line of the patient’s mouth. The next tooth/teeth to move is/are not scheduled to begin moving until at least approximately the half way stage of its respective previously-scheduled tooth/teeth.[9]

[8] ’444 patent, 2:53-55.
[9] ’444 patent, 10:19-28.

35. The ’444 patent states that “FIG 6A is a diagram of one exemplary embodiment of a ‘Mid-Line Shift’ pattern for moving the skewed teeth of a patient during an orthodontic treatment.”[10] Figure 6A is reproduced below.

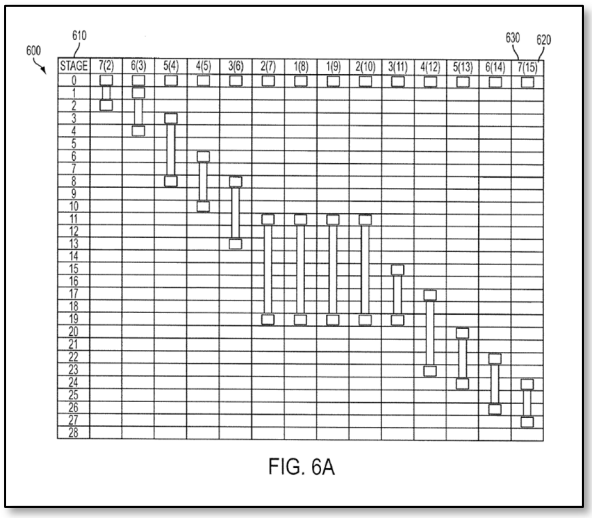


FIG. 6A

36. The ’444 patent also states that “FIG 6B is a diagram of an exemplary embodiment of another ‘Mid-Line Shift’ pattern for moving the skewed teeth of a patient during an orthodontic treatment.”[11] Figure 6B is reproduced below.

[10] ’444 patent, 2:47-49; ’444 patent, 10:57-67 (“FIG. 6A is a diagram illustrating an example of a ‘mid-line shift’ pattern 600 for teeth skewed (to the patient’s left) less than about 1.0 mm in accordance with one exemplar embodiment of the invention. Similar to above, column 610 illustrates the number of stages needed to correct the patient’s teeth. In this example, the patient requires 26 stages of treatment before the patient’s teeth reach their final position in stage 27. Moreover, similar to FIGS. 3-5, FIG. 6A uses the standard teeth numbering system 620 to identify each of the teeth and a position 630 to illustrate the respective positioning of the teeth on the patient’s arch.”).

[11] ’444 patent, 2:50-52; ’444 patent, 11:17-27 (“FIG. 6B is a diagram illustrating an example of an ‘mid line shift’ pattern 600’ for teeth skewed (to the patient’s right) more than about 1.0 mm in accordance with one exemplary embodiment of the invention. Similar to above, column 610 illustrates the number of stages needed to correct the patient’s teeth. In this example, the patient requires 29 stages of treatment before the patient’s teeth reach their final position in stage 30. Moreover, similar to FIG. 6A, FIG. 6B uses the stand teeth numbering system 620 to identify each of the teeth and a position 630 to illustrate the respective positioning of the teeth on the patient’s arch.”).

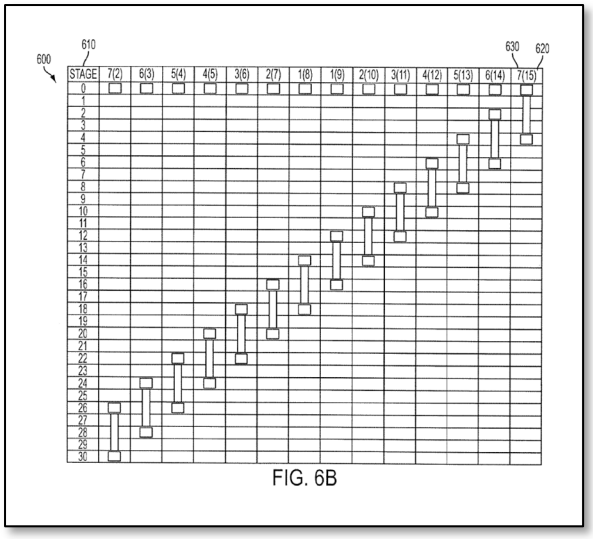


FIG. 6B

B. An Optimal Number of Stages

37. As the Abstract of the '444 patent states, the purported "invention also includes techniques for determining an optimum number of stages for the treatment based on the schedule of movement."[12]

38. Figure 11 of the '444 patent "is a flow diagram of one exemplary embodiment of a method 1100 to stage the movement of one or more teeth in accordance with one exemplary embodiment of the invention."[13] Figure 11 is shown below.

[12] '444 patent, Abstract.
[13] '444 patent, 14:41-43; '444 patent, 3:5-6 ("FIG. 11 is a flow diagram of a method for scheduling the movement of teeth during an orthodontic treatment.").

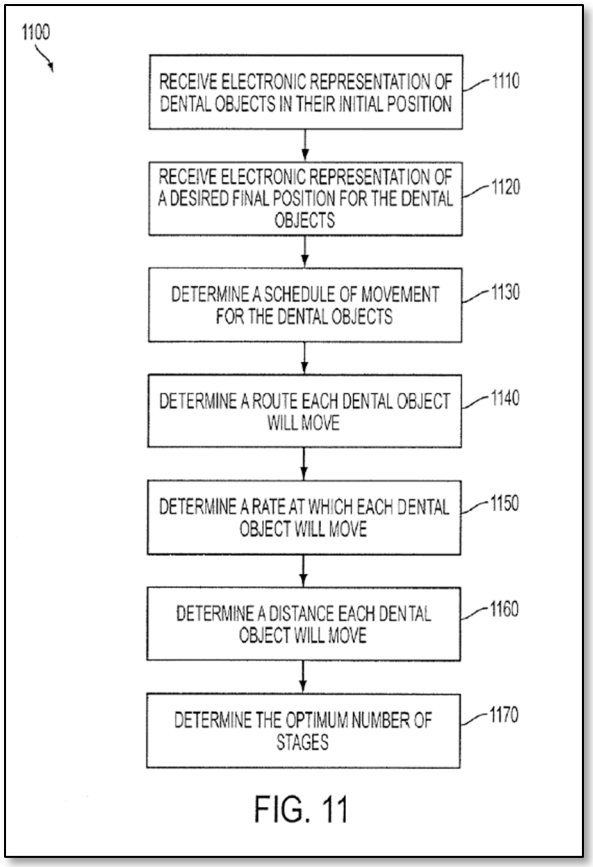


FIG. 11

39. The last box (or step) in Figure 11 is "determine the optimum number of stages."[14]

40. The other boxes in Figure 11 constitute aspects, factors, and/or steps that impact what would constitute the optimum number of stages. For example, the optimum number of stages would be impacted by the schedule of movement for the dental objects, the route each dental object will move, the rate at which each dental object will move, and the distance each dental object will move. As an example, the rate at which each dental object will move will determine on patient's individual "comfort level and/or tolerance for pain" and require a balancing of ensuring teeth movement that "does not cause significant discomfort or pain to the patient, but allows fast, efficient movement."[15] As another example, the schedule of movement, route, and distance

[14] '444 patent, 14:41-59 (referring to each entry as a "step").
[15] '444 patent, 7:18-26.

travelled will depend on what movement pattern is utilized (e.g., A-Shaped, V-Shaped, or any other pattern) and what collision avoidance techniques are utilized.[16]

41. The '444 patent further states that:

> The optimum number of stages, in one embodiment, is determined based upon the determinations of step 1130 through step 1170. Furthermore, step 1170 includes factoring any staggering, slowing down/interim key framing, and/or round-tripping needed to place the patient's teeth in their desired final position. For example, in FIGS. 3-9 the optimum number of stages needed for these respective examples factored in the type of pattern needed, the rate, the path, the distance, staggering, slowing down/interim key framing, and/or round-tripping in determining the optimum number of stages for treating the patient's teeth. As one skilled in the art will recognize, the optimum number of stages will likely differ from patient to patient.[17]

42. The '444 patent also states "[i]n one exemplary embodiment, determining the optimum number of stages includes determining the minimum number of stages needed for each respective tooth to be placed in its final, desired position."[18]

43. It further states that:

> In another exemplary embodiment, the optimum number of stages is the largest number of the minimum stages needed to place the patient's teeth in their final, desired position. For example, a patient has three teeth that need to be moved during treatment, wherein the first tooth needs 4 stages to move to its final position, the second tooth needs 9 stages to move to its final position, and the third tooth needs 6 stages to move to its final position. Assuming each of these teeth is scheduled to begin moving at the same stage, the optimum number of stages is 9 since this is the minimum number of stages needed to place all of the teeth in their final position.[19]

---

[16] For example, the '444 patent states that "in cases where teeth may collide with or obstruct one another during movement, the program is configured to suitably stagger, slow down and/or plan-round-tripping for the teeth movement." '444 patent, 12:41-44. Whether a collision is avoided by staggering, slowing down, round tripping, or some combination of these techniques would impact the schedule of movement, the route, and distance the teeth travel.

[17] 444 patent, 14:59-15:5

[18] '444 patent, 15:6-9.

[19] '444 patent, 15:9-20.

V. Construction of Disputed Terms

A. The Pattern Terms

44. Claims 8-11, 22-25, and 36-39 of the '444 patent and claim 3 of the '456 patent each recite at least one of the above Pattern Terms. For example, claim 8 of the '444 patent recites:

> The computer-implemented method of claim 1, wherein the determining the order of movement step comprises ordering the movement of the dental objects to form a V-shaped pattern.

45. As another example, claim 3 of the '456 patent recites:

> The method of claim 1, wherein the schedule of movement includes one of an all-equal pattern, an A-shaped pattern, a V-shaped pattern, a mid-line shift pattern, or a M-shaped pattern.

46. I understand that the parties have proposed constructions for the Pattern Terms as summarized in the table below.

Term	ClearCorrect's Proposed Construction	Align's Proposed Construction
"V-shaped pattern" ('444 patent, claims 8, 22, 36; '456 patent, claim. 3)	A pattern where teeth having the same and/or similar positions on the arch will be moved beginning at the same stage, and will move continuously until they reach their final position, and where the most posterior-positioned teeth move first (e.g., the molars, or teeth in position 7 and/or 8) then the next anterior-positioned teeth move sequentially until all of the teeth reach their final position, with the next anterior-positioned tooth not scheduled to begin moving until at least approximately the half-way stage of its respective posterior-positioned tooth	No construction is necessary.

"A-shaped pattern" ('444 patent, claims 9, 23, 37; '456 patent, claim 3)	A pattern where teeth having the same and/or similar positions on the arch will be moved beginning at the same stage, and will move continuously until they reach their final position, with the most anterior-positioned teeth (e.g., the incisors, or teeth in positions 1 and/or 2) moving first and then the next posterior-positioned teeth sequentially moving until all of the teeth reach their final position	No construction is necessary.
"M-shaped pattern" ('444 patent, claims 10, 24, 38; '456 patent, claim 3)	A pattern where teeth having the same and/or similar positions on the arch will be moved beginning at the same stage, and will move continuously until they reach their final position, with teeth between the anterior teeth and the posterior teeth (e.g., the bicuspids, or teeth in positions 4 and/or 5) and both the adjacent anterior and/or adjacent posterior teeth then sequentially moving until all of the teeth reach their final position	No construction is necessary.
"mid-line shift pattern" ('444 patent, claims 11, 25, 39; '456 patent, claim 3)	A pattern where tooth movement begins on one side of the patient's arch to center the teeth with respective to the mid-line of the patient's mouth, with the next tooth/teeth to move not scheduled to begin moving until at least approximately the half way stage of its respective previously scheduled tooth/teeth	No construction is necessary.

47. In my more than forty years of practicing as an orthodontist, I have never used, seen, or heard these Pattern Terms. Based on my experience in practicing and teaching, these are not terms that appear in common orthodontic textbooks, nor are they part of teaching curriculums for orthodontic training. A practicing orthodontist or someone working alongside someone in orthodontics would not know these terms. By way of example, even with my more than 40 years of experience, if someone told me that a treatment plan used an "A-shaped" pattern, I would not know what is meant.

48. Instead, these terms appear to be terms that Align has come up with. For example, the Treatment Planning Patents, after describing potential use cases for these different patterns, states that "any other treatment patterns can be suitably selected from other orthodontic treatment patterns … such as those patterns disclosed in U.S. Pat. No. 6,729,876, entitled 'Tooth Path Treatment Plan' issued on May 4, 2004 and assigned to Align Technology, Inc."[20] In the '876 patent, Align uses some terms that overlap with those in the Treatment Planning patents in this case (e.g., A-shaped, V-shaped, and M-shaped), but also includes some different terms (e.g., W-shaped, and symmetric staircase pattern).[21]

49. In light of these terms not being used in the industry, having no common meaning, and their names not being descriptive enough to understand what is actually meant by these terms, one would need to consult and rely on the definitions in the specification to understand what these terms mean.

50. As I identified in Section IV.A, the specification includes language that defines these terms. These definitions in the specification mirror the definitions that ClearCorrect has proposed to be the correct constructions. I agree with ClearCorrect that these terms should be defined based on the contours in the specification.

B. "an optimal number of stages for the order of movement of the dental objects"

51. As shown below, claims 5, 19, and 33 of the '444 patent require determining "an optimal number of stages for the order of movement of the dental objects."

- **Claim 5:** The computer-implemented method of claim 1, further comprising determining, by the host computer, an optimal number of stages for the order of movement of the dental objects.

[20] *See* '444 patent, 5:61-67.
[21] U.S. Patent No. 6,729,876, 2:44-49.

- **Claim 19:** The system of claim 15, further comprising means for determining an optimal number of stages for the order of movement of the dental objects.
- **Claim 33:** The machine-readable medium of claim 29, further comprising instructions to determine an optimal number of stages for the order of movement of the dental objects.

52. I understand that the parties have proposed construing that phrase as summarized in the table below.

Term (claims)	ClearCorrect's Proposed Construction	Align's Proposed Construction
an optimal number of stages for the order of movement of the dental objects '444 patent, claims 5, 19, 33	Indefinite	the largest number of the minimum stages needed to place the patient's teeth in their final, desired position

53. I have reviewed the common specification of the Treatment Planning Patents, and it does not provide any clear definition or direction as to how to determine an "optimal" number of stages for the order of movement of the dental objects. For example, as I explained above, based on the specification, the optimum number of stages would be impacted by a number of factors, including the schedule of movement for the dental objects, the route each dental object will move, the rate at which each dental object will move, and the distance each dental object will move. Nowhere does the specification describe how to weigh these and other factors that may go into the determination of the optimal number of stages. That determination is a subjective determination that different orthodontists would make in different ways, and there is no objective method or metric described in the patent for making that determination.

54. The patent does include certain claims—claims 6, 20, and 34 which are dependent claims from claims 5, 19, and 33—that describe one method of determining the optimal number of stages:

- determining a total distance each respective dental object will move;

- dividing the total distance for each dental object by its respective maximum speed to determine a number of movement stages for each dental object;
- determining a number of non-movement stages for each respective dental object;
- adding the number of movement stages to the number of non-movement stages for each dental object to determine a minimum number of stages for each respective dental object; and
- selecting the largest of the minimum number of stages.

But these steps are not included in the claims at issue here (claims 5, 19, and 33), which refer more generally to determining an optimal number of stages without disclosing any further steps or clarification as to how to make that determination. As noted above, there is no objective method or metric described in the patent for making that determination.

55. This is consistent with my more than 40 years of experience in the field of orthodontics. For example, to determine the optimal number of stages for a patient's treatment plan, I would consider several factors, including at least the following:

- **The Patient's Pain Tolerance/Sensitivity to Teeth Movement.** To balance potential pain or sensitivity associated with teeth movement, I may use more stages to move the teeth at a slower rate to reduce pain associated with teeth movement.
- **Cost.** Needing more stages (and hence more aligners) increases the cost associated with aligner treatment. Therefore, for patients who are more budget conscious or are looking for a cheaper treatment option, I may use fewer stages (and therefore try to achieve more teeth movement per stage) than I would with a customer that would be willing to pay a bit more for more stages.
- **The Patient's Timing Goal.** Depending on when a patient first comes to me and how much time they have to reach their treatment goal, I may increase or decrease the number of aligners I would recommend. For example, if a patient has his wedding coming up, I may try to move the teeth at a faster rate. This would impact the number of stages (and aligners).
- **The Patient's Teeth.** Putting aside a patient's pain tolerance and level of sensitivity to teeth movement, some patients have teeth that can move faster than others (for

example, younger patients have less restrictive bone density that allow for quicker teeth movement, while older patients tend to have greater bone densities that require slower movement). Similarly, where roots are located (e.g., the proximity of the roots to other structures in the mouth and the boundary conditions of the alveolar bone housing the teeth within the cortical bone) would impact the ability for the teeth to move, which then in turn impacts the number of stages that are needed.

- **The Patient's Cooperation (i.e., Actual Use of the Aligner).** Depending on whether the patient is expected to wear the aligner properly (e.g., for the right number of hours per day), an orthodontist may need to make a judgment call regarding whether to use more or fewer stages to ensure that the patient's teeth move appropriately in reality and not just in an idealized treatment plan that assumes perfect compliance.

- **The Teeth Movement Path.** The number of stages needed depends on what movement paths are chosen, and there are a variety of different approaches that orthodontists may use in designing a movement path. For example, the movement of teeth in an aligner system has a degree of unpredictability to it. As one example, when you need to rotate a tooth, it is challenging to predict how many stages are needed to rotate the tooth, and some orthodontists may think more stages are needed while others may think fewer stages are needed. Indeed, actual tooth movement is more like tacking a 'sailboat' (i.e., requiring variations and adjustments in the path between point A and point B) rather than a 'speed boat' (i.e., using a straighter path from point A to point B. When dealing with tooth movement on a real patient, orthodontists will often differ on issues such as the best movement paths (and therefore on the number of stages required). An orthodontist's judgment on these issues will depend on the orthodontist's knowledge, experience, ability, and even what expert that the orthodontist follows in his or her philosophy of diagnosis and treatment.

56. There is no objective measure or metric in the field of orthodontics to determine how to balance these and other factors to determine an optimal number of stages. Indeed, if you asked five orthodontists treating the same patient what would be the optimal number of stages for the order of movement of teeth in the patient's treatment plan, you would rarely expect them to agree on the number of stages, and you could quite often expect to get five different answers. The meaning of "an optimal number of stages for the order of movement of the dental objects" in the '444 patent is therefore entirely uncertain to me, despite my decades of experience in the field of orthodontics.

VI. Right to Supplement

57. I reserve the right to supplement my conclusions in the future, to respond to any argument that Align raises, and to consider new information as it becomes available to me.

VII. Materials Considered

58. In addition to any material cited in this Declaration, I have reviewed and considered the materials listed below.

Description	Bates Number
U.S. Patent No. 6,729,876	CC_ALGN_00007637- CC_ALGN_00007671
U.S. Provisional Application No. 60/824,022	CC_ALGN_00020068- CC_ALGN_00020122
U.S. Provisional Application No. 60/824,024	CC_ALGN_00020123 - CC_ALGN_00020186
U.S. Patent No. 8,038,444	
U.S. Patent No. 10,456,217	
U.S. Patent No. 10,524,879	
U.S. Patent No. 11,369,456	
File History for U.S. Patent No. 10,456,217	ALGN00001020- ALGN00001410
File History for U.S. Patent No. 10,524,879	ALGN00001411- ALGN00001822
File History for U.S. Patent No. 11,369,456	ALGN00007541- ALGN00010913
File History for U.S. Patent No. 8,038,444	ALGN00011450 - ALGN00014839
File History for U.S. Patent No. 11,717,381	CC_ALGN_00020187- CC_ALGN_00020436
File History for U.S. Patent No. 10,402,631	CC_ALGN_00020437- CC_ALGN_00020713
File History for U.S. Patent No. 9,326,830	CC_ALGN_00020784- CC_ALGN_00021291
File History for U.S. Patent No. 11,950,777	CC_ALGN_00021292- CC_ALGN_00021488
File History for U.S. Application No. 18/481,798	CC_ALGN_00020714 - CC_ALGN_00020783

Dated: October 31, 2024

Dr. William Harrell, Jr.

EXHIBIT A

CURRICULUM VITAE for:

William Edward Harrell, Jr., D.M.D.
Board Certified Orthodontist (American Board of Orthodontists)
Certified in Dental Sleep Medicine
Temporomandibular Joint Disorders (TMD/TMJ) & Cranio-Facial Pain
5030 US Highway 280 Suite D
Alexander City, Alabama 35010
Office: 256-234-6353 FAX: 256-329-4335
Email: drh@drharrell.com

Updated 10-23-2024

Professional Education:

College: University of Alabama
B.S. – Chemistry & Math , Minor – Biology, 1967 – 1971

Dental School: University of Alabama School of Dentistry, Birmingham, Alabama
1971 – 1975 earned DMD Degree

Orthodontic Post-Doctoral Residency: Certificate in Orthodontics, University of Pennsylvania, School of Dental Medicine
1975 – 1977

Board Certification: **Board Certified by the American Board of Orthodontics (ABO) 1989.**

Qualified Dentist: **American Academy of Dental Sleep Medicine, in process of Board Certification**

Accomplishments: Began Orthodontic Practice in Alexander City, AL August 25, 1977

Practiced part-time and taught with the late Dr. Bill Farrar & Dr. Bill McCarty of Montgomery, AL, World-renowned pioneers in the area of TMJ/TMD diagnosis & treatments. Founders of the Normandie Study Group for TMJ Dysfunction. I contributed how orthodontic treatment and airway issues related to TMD patients, 1979-1985

Adjunct Assistant Professor at the University of Alabama Birmingham (UAB) School of Dentistry Department of Orthodontics.

Professional Organizations: Board Certified by The American Board of Orthodontics (ABO) – 1989

Member of the American Academy of Dental Sleep Medicine

Member of the American Academy of Sleep Medicine

College of Diplomates of the ABO (CDABO)

Member of the Southeastern Dental Practice Research Network (DPBRN) (www.sedprn.org) – University of Alabama Birmingham, School of Dentistry

Affiliate member of the American Academy of Oral and Maxillofacial Radiologists

The Farrar-Norgaard Radiological Society

The Royal Society of Medicine – Great Britain

The Foundation for Orthodontic Research (FOR)

The Orthodontic Education and Research Foundation (OERF)

Mid West Angle Orthodontic Society (invitation only)

American Dental Association (ADA)

Alabama Dental Association (AlDA)

Ninth District Dental Society of Alabama

American Association of Orthodontists (AAO)

Southern Association of Orthodontists (SAO)
Alabama Association of Orthodontists (AlAO)

American Equilibration Society

The Roth/Williams International Study Group

Honored Member Director – Who's Who in Executives and Professionals

Offices and Positions Held: President – Alabama Asso. of Orthodontists 1990 – 1991

Vice- President – Alabama Asso. of Orthodontists 1989 – 1990

Secretary/Treasurer – Alabama Asso. of Orthodontists 1988 – 1989, 1997

President – University of Pennsylvania Orthodontic Alumni Asso. 1999 – 2000

President – Ninth District Dental Society of AL 1987 – 1988

Board of Trustees – Alabama Dental Asso. 1988, 1994 – 2002

House of Delegates – Alabama Dental Asso. 1987 – 1989, 1998 – 2002

Chairman – Alabama Dental Association (ALDA) TMJ/TMD Committee 1990 – present

Member Orientation Committee Member Southern Asso. of Orthodontists - 1985 – 1990

Committee Member for Alabama Dental Asso. Council on Dental Health of the State Committee of Public Health in Alabama - 1992 - 1997

Committee member – Council on Information Technology (COIT) of the AAO, 2001 - 2003

Committee member – Technology Comm. of the SAO, 2001 - 2005

Committee Member – American Dental Asso. – Standards Committee on Dental Informatics – (SCDI) representing the AAO, 2002- present

Peer Review Committee – Alabama Dental Asso. 1999 – present

Member of Council on Dental Care Programs – Alabama Dental Asso. 2002 – 2006

Alabama Director – Board of Directors Southern Asso. of Orthodontists - 1995 – 1997

The Southern Asso. of Orthodontists committee member representative of the Technology Visioning Task Force Committee for the AAO- 1999 – 2001

Associate Medical Staff – Russell Medical Center Alexander City, Alabama

Technology Conference Committee member for the AAO 2006

Technology Conference Committee member for the AAO 2008

Work Group Member – Southeastern Telehealth Resource, 2016 – present

Member of the American Dental Association's (ADA) Children's Airway Screener Taskforce (CAST) 2018 - present

Chairperson of the ConeBeam CT (CBCT) Standards Committee working with RadSite to develop standards practices, protocols and certification of CBCT units for the insurance reimbursement. 2018-present

Chair & member of ADA SCDI Working Group 13.8 Augmented/Artificial Intelligence (AI) in Orthodontics. 2021-present

Member of ADA SCDI Working Group 11.1 Interdisciplinary WG 2000-present

Member of ADA SCDI Working Group 11.6 Orthodontic WG 2000-present

Teaching Experience:

Adjunct Assistant Professor at UAB Orthodontic Dept.

Guest Lecturer – Orthodontic Dept. University of Alabama

Guest Lecturer – Orthodontic Dept. University of Pennsylvania

Guest Lecturer – Vanderbilt Medical School to the Farrar-Norgaard Radiological Society - 1987

Guest Lecturer – University of Minnesota Medical School to the Farrar-Norgaard Radiological Society – 1986

Scientific speaker - The Alabama Dental Asso. – *TMD & Orthodontics* - The William B. Farrar Memorial Lecture - 1987

Numerous Lectures and Instructor of the Normandie Group, with the Pioneers in TMJ Disorders, Drs. Bill Farrar and Bill McCarty, in regard to TM Disorders
1979 – 1985

Scientific speaker - The American Asso. of Orthodontists (AAO)

Scientific speaker - The Southern Asso. of Orthodontists (SAO)

Scientific Speaker at the American Association of Orthodontists (AAO) Meeting – Technology Section May 6, 2001, Toronto, Canada - "3D Imaging and The Future of Orthodontics – In Search of Anatomic Truth"

Scientific speaker – The Foundation for Orthodontic Research (FOR), Nassau, Bahamas, May 2002

Scientific speaker, *Orthodontics-2010*, University of North Carolina, Sept 27 & 28, 2002

Scientific speaker, Academy of Pediatric Dentistry, University of AL Birmingham Dental Alumni Meeting, "In Search of Anatomic truth: 3D technology and the future of Dentistry", Feb 7,2003.

Scientific Speaker for AAO meeting, Hawaii, May 2003

Speaker 31st Moyer's Pre-Symposium June 27, 2004. University of Michigan, Center for Human Growth and Development

Scientific Speaker for AAO meeting, Orlando, FL, May 2004

Scientific Speaker for AAO meeting, San Francisco, CA, May 2005

Speaker SIDO (Italian Orthodontic Society) Spring Meeting "Innovation Technology and Practice management" March 4 & 5, 2005

Angle Society – Feb 2006

UAB – Dental School - Conebeam CT imaging in Orthodontics, March 24, 2006

Italian Orthodontic Group, Ferrara, IT – 3D Imaging in Orthodontics Sept 2006

University of Pennsylvania, Clinic Day lecturer 3D Imaging in Orthodontics Sept 14, 2006

Southern Asso Orthodontists, Speaker, “3D Imaging in Orthodontics”, Oct 26, 2006.

Kodak User Meeting, “3D Imaging in Orthodontics” March 10, 2007

1st International Congress on 3D Imaging in Dentistry, New York, NY, “Completing the 3D Picture”, July 13-14, 2007

CADABO Meeting, Big Sky MT, “3D Imaging”, July 13-19, 2008.

Virginia Orthodontic Meeting, Bermuda, “3D Imaging in Orthodontics”, June 27-28, 2008

An Interdisciplinary Update on Dental and Facial Esthetics, Joint Conference of AAO and AAOMS, Jan 22-24, 2010, Speaker: *“3D facial imaging and predictive morphing”*

Illinois Society of Orthodontists, Nov 15, 2010. Speaker: *3D Technology in Orthodontic Practice**

Lecturer American Association of Orthodontists (AAO) 112th Session, Hawaii, May 2012, A New Paradigm in Orthodontic Diagnosis and Treatment Planning.

Lecturer Alabama Association of Sleep Professionals, Pensacola, FL May 8 & 9, 2015
Topic: Dental alternatives for the CPAP intolerant patient and early recognition of Allergy/Airway signs in children, its effect on cranio-facial growth & early orthodontic treatment effecting Airway development.

Lecturer American Association of Orthodontists, Orlando, FL May 2016
Topic: “Dental alternatives for the CPAP intolerant patient and early recognition of Allergy/Airway signs in children, its effect on cranio-facial growth & early orthodontic treatment effecting Airway development.”

Numerous lectures on Sleep Disordered Breathing, Sleep Apnea and Upper Airway resistance from 2017 – 2020. Some on-line others “live”.

Lecturer AAO Annual Meeting May 2022 Miami, FL “Pediatric Sleep Disorders and its relationship to orthodontic practice”.

Lecturer (full day) Alabama Dental Association (AlDA) annual meeting in Gulf Shores, AL June 9, 2022. “Growing into Breathing Problems: The Quest for Collaborative Lifetime Solutions” with Dr David McIntosh and Dr. Jerry Simmons, MD.

Lectures to UAB Orthodontic Residents on Airway / TMJ / Orthodontics / CBCT / 3D Imaging / Early Treatment, Every 2nd Friday of the month 2021, 2022, 2023

Lectures on Airway Circle, numerous Guest Lectures Virtual 2022, 2023

Lecture Virtual Oct 5th, 2023 – Airway and Orthodontics, NAMSCON, India

Lecture Live, UAB Hygiene Conference Dental School Wynfrey Hotel, August 16-17, 2024. With Karen Davidson 4 phase RM and orthodontics/dentistry.

Lecture Live, AGD Alabama, San Destin, FL Sept 6 – 7, 2024, With Karen Davidson 4 phase RM and orthodontics/dentistry.

Future - Course LIVE 1st ANNUAL - 3 days March 2025, UAB Medicine and Dentistry With Karen Davidson 4 phase RM and orthodontics/dentistry, Dr David Gozal, MD, Dr. Jerry Simmons, MD, others

Published Articles:

Harrell, WE ,"A Fixed Functional and TMJ Treatment Appliance" *Journal of Clinical Orthodontists* June 1988.

Harrell, WE, "In Search of Anatomic Truth: 3D Digital patient modeling and the future of Orthodontics" *AJODO - TechnoBytes Section, Vol 122,No. 3,* Sept 2002

American Journal of Orthodontics& Dentofacial Orthopedics Front cover of the Oct. 2002 issue along with Editorial

Adams GL, Gransky S, Miller AJ, **Harrell WE**, Hatcher DC, "The Comparison between traditional Two-dimensional Cephalometry and a three-dimensional Approach on dry skulls", *American Journal of Orthodontics Dentofacial Orthopedics, Vol 126, #4, Oct 2004.*

Harrell, WE ,"Limitations of Two-Dimensional Cephalometric Analysis in Orthodontic Diagnosis and Treatment Planning: The need for Three-Dimensional Diagnosis", Currents, Quarterly Publication of the American Association of Dental Maxillofacial Radiographic Technicians (AADMRT), Summer 2003. See link below: **http://www.aadmrt.com/currents/members/ARCHIVE/PDF/AADMRT%20Newsletter%20Summer%202003.pdf**

Harrell, W, Stanford, S, Bralower, P, ADA initiates development of orthodontic informatics standards, AJODO, Vol 128, #2, August 2005.

Harrell, WE, "Three-Dimensional diagnosis & treatment planning: The use of 3D facial imaging and conebeam CT in Orthodontics and Dentistry", Austral Asian Dental Practice, pgs 112-122, July/August, 2007,

Harrell, WE, Lane, C, "Completing the 3D Picture", AJODO, 133 #4, April, 2008. *American Journal of Orthodontics & Dentofacial Orthopedics* Front cover of the April, 2008 issue

PCSO NewsWire June 2009. **Harrell**, "Should we use 3D imaging for "routine orthodontic cases"? Part I (2D info) at **http://www.pcsortho.org/newswire/June-09.cfm**

PCSO NewsWire . **Harrell "**Should we use 3D imaging for "routine orthodontic cases"? Part II (3D info) at **http://www.pcsortho.org/newswire** to be published in Sept 2009 issue PCSO NewsWire.

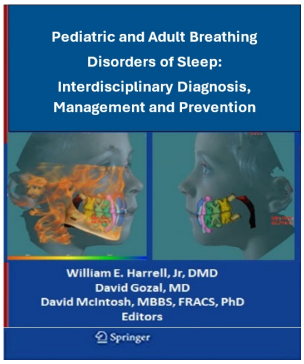
S Kapila, R S Conley, **W E Harrell, Jr** **The current status of cone beam computed tomography imaging in orthodontics** Dentomaxillofac Radiol. 2011 Jan; 40(1): 24–34.

Harrell WE, Tatum T, Koslin M, "Is Centric Relation Always the Position of Choice for Temporomandibular Disorders? A Case Report of How TMD and Airway Dimension May Be Associated", Compendium, Volume 38, Issue 4, April 2017 **https://www.dentalaegis.com/cced/2017/04/is-centric-relation-always-the-position-of-choice-for-tmds-case-report-of-how-tmd-and-airway-dimension-may-be-associated**

Harrell WE, The Breathing-Smile Connection: The Intersection of Airway Health in Orthodontics, Dental Sleep Practice Journal, Spring 2024.

Textbooks / Chapters: **Textbooks**

Pediatric and Adult Breathing Disorders of Sleep: Interdisciplinary Diagnosis, Management, and Prevention Eds. **Harrell W,** Gozal D, Mcintosh D, Springer Publishing in press 2024 or 2025.



Chapters

Harrell, WE ,"*Diagnosis goes Digital*", In: Information Technology and Orthodontic Treatment – 29th Annual Moyers Symposium 2002, University of Michigan Center for Human Growth and Development, co-author with Dr. David Hatcher, pgs.79-91, 2003.

Harrell, WE ,"*Future of Imaging for Orthodontics",* Chapter 15, pg. 405-413, In: Essentials for Orthodontic Practice, Editors: Drs. Michael Riolo & James Avery ,2003.

Harrell, WE, "*3D Imaging for Orthodontics",* new Chapter, In: Essentials for Orthodontic Practice, Editors: Drs. Michael Riolo & James Avery, New digital version in press for 2006.

Harrell, WE, "3D Cephalometric Imaging" chapter in Radiographic Cephalometrics: from basics to 3D, Editor Jacobson, Publisher Quintessence, 2006.

Harrell WE, Scarfe, WC, Chapter "3D Imaging in Orthodontics". in Cone Beam Computed Tomography Maxillofacial 3D Imaging Applications, Springer Publishing, Berlin, Farman, Allan G.; Scarfe, William C. (Eds.) 2011

5th Edition Orthodontics Current Principles and Techniques, Graber, Vanarsdall, Vig (Eds), Chapter 3D Imaging in Orthodontics, by **Harrell,** Hatcher & Mah. Publisher Elsevier/Mosby, 2011.

Harrell WE, Lane C, Duncan K, Chapter "Image Fusion". Cone Beam Computed Tomography Maxillofacial 3D Imaging Applications, Springer Publishing, Berlin, Farman, Allan G.; Scarfe, William C. (Eds.) 2011

Research:

Clinical and Scientific research preformed in conjunction with the Normandie Group for the Study of TMJ Dysfunction – Directors Dr. Bill Farrar and Dr. Bill McCarty, Montgomery, AL (1979 – 1985)

Secured Funding for Phase I Small Business Innovative Research (SBIR) Grant through NIH/NIDR – DE09619 "Three-dimensional Stereoscopic Cephalometric and Video Imaging for Orthodontists, Oral Surgeons, & Plastic Surgeons" - Phase I Funded 1991

Research in progress for "Early detection & recognition of Allergy/Airway Signs (Biomarkers) on 3D facial imaging and early treatment of obstructive airway issues in children.

Dental Practice Research Network (DPBRN) Study on Anterior Open Bite, UAB (www.sedprn.org), 2015-2017

Dental Practice Research Network (DPBRN) Study on TMJ Disorders, UAB in Process 2017-2018.

The use of Telemonitoring and a Smart Phone App to track side effects of tooth and jaw movement of Oral Appliances for Sleep Apnea. The Dental Monitoring application was originally designed for the patient to take calibrated 2D photos on their Smart Phone and the doctor can then track these changes without the patient having to visit the office. Dr. Harrell is the first to use this technology to track side effects for Oral Appliance Therapy (OAT) for Sleep Apnea via telemonitoring.

Clinical research using 3Shape intraoral scanner for monitoring dental & jaw changes from the use of Oral Appliances for Sleep Apnea.

Clinical research using 3Shape intraoral scanner for diagnosis & treatmenr of Sleep Disorders Breathing in children

Clinical research using 3Shape intraoral scanner for OSA appliance design.

Working with UAB Bioengineering Dept. to develop a remotely controlled temporary appliance for use during a sleep study (PSG) to determine proper bite registration for maximum efficiency of OAT.

Dr. Harrell is the <u>First</u> in many areas of Orthodontics, TMJ Therapy, & Dental Sleep Medicine and in developing new and innovative diagnosis and treatment techniques.

1. We were the First practice in Alabama to use InvisAlign , est 1997
2. We are the First in Alabama to have ConeBeam CT (CBCT). Acquired in 2005.
3. We are the First in the USA to have both CBCT and 3D facial imaging. Acquired in 2005.
4. We are the First in Alabama to use the Dental Monitoring ® system to remotely monitor orthodontic tooth movement (Telemonitoring) by using the DM Smart Phone App.
5. We are the First in the USA to use the Dental Monitoring ® system to remotely monitor tooth and jaw movement in patients who are using an Oral Appliance for the treatment of Obstructive Sleep Apnea. Dr. Harrell is working with DM on creating the software and protocol for this application.
6. Dr. Harrell has developed original techniques for the treatment of TMJ patients who also need Orthodontic and/or Surgical treatment. HAP appliance, use of the SVED appliance along with braces to hold TMJ position and allow for tooth movement.
7. Dr. Harrell is currently working with the Bioengineering Dept at UAB for the development of a device to be used during a sleep study to remotely and accurately determine the most ideal jaw position needed for treating Sleep Apnea patients. Presently this jaw position is determined by an anecdotal clinical feel and with no scientific basis.
8. Dr. Harrell is the First in USA to use 3D facial imaging to detect physical signs on the face (Biomarkers) that relate to allergy/airway and sleep breathing disorders in children. Dr. Harrell is presently developing standardization protocol of 3D facial imaging and 3D analysis of facial regions that relate to facial growth and development and for physical signs of autism, facial growth abnormalities, airway and other related problems.
9. Dr. Harrell is one of the first to use the Healthy Start early treatment system for airway and arch development in children from 2 – 8 years of age.
10. Dr. Harrell worked with **THE TMJ pioneers,** Dr. Bill Farrar & Dr. Bill McCarty in Montgomery, AL (Normandie Study Group of TMJ Dysfunction) from 1979 – until Bill Farrar's death in 1985.
11. Dr. Harrell worked under Dr. Christian Guilleminault, MD **"the father of Sleep Medicine"** and colleagues at Stanford University, where Sleep Apnea was discovered and researched.
12. Dr. Harrell worked with Dr. Steve Schendel , DMD, MD former Chair of Plastic Surgery at Stanford U on Sleep Disorders Breathing and Sleep Apnea. Stanford University is where Sleep Apnea was discovered.